JUL 3 1 2001

Summary of Safety and Effectiveness

Introduction

This Summary of Safety and Effectiveness document is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by

Unisensor AG
Bahnstrasse 12a, CH-8544 Attikon, Switzerland

USA Contact Person

Robert N. Clark
Medical Device Regulatory Advisors
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

November 14, 2000

Trade Name of Device

UniTip Gastrointestinal Pressure Sensor Catheter

Common Name of Device

Catheter Pressure Transducer

Classification Name

System, Gastrointestinal Motility (Electrical)

510(k) Classification

21CFR§876.1725 Class II

Device Description and Intended Use

The devices are intended for use in the evaluation and diagnosis of gastroenterological dysfunction related to muscle tonus and the coordination of contractions between muscle groups. Pressure information is provided at multiple sensor sites. Secondary to the pressure information is measurement of pH in the stomach and esophagus. SOM probes are intended for use within the Sphincter of Oddi zone.

Comparison to Predicate Devices

The device is equivalent in safety and performance to prior legally marketed devices. In particular it is equivalent to:

K980980 - Motility Probes: Models P31-P38, P40-43, & P50, Manufactured by Konigsberg Instruments, Inc.

K900058 - Wilson-Cook Biliary Motility Catheter, Manufactured by Wilson-Cook Medical, Inc.

K792177 - Millar MIKRO-TIP Catheter Transducer, Manufactured by Millar Instruments, Inc.

Non-Clinical Testing

The requirements of the following standards have been used in part to establish substantial equivalence:

EN 1441 "Medical Devices – Risk Analysis"

EN 60601-1-2 "Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests"

EN 30993-1 / ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing"

The company did not conduct, nor depend on, clinical studies in order to establish substantial equivalence.

Risk Management

This device has been designed to either completely eliminate or mitigate all known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program. One or more of the following means (in order of preference) was used to implement mitigation of health hazards identified by the risk management program:

1. Design modifications.
2. Detection of hazard conditions and alerting of the user.
3. Identification of any potentially undetectable health hazard conditions in the instructions for use or other device labeling.

The user must be qualified in gastrointestinal diagnostic procedures, trained in the insertion and use of gastrointestinal manometry catheters, and must be familiar with all labeling and instructions for use associated with the device. The company believes many device health hazards are due to user error and failure to follow instructions for use.

Unisensor AG believes that the UniTip Gastrointestinal Pressure Sensor Catheter products are safe and effective when used as instructed by knowledgeable and trained personnel, and performs as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Unisensor AG
c/o Mr. Robert N. Clark
President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Avenue
GOLDEN CO 80401-4604

Re: K003580
Unitip Pressure Sensor Catheters
Dated: April 27, 2001
Received: May 2, 2001
Regulatory Class: II
21 CFR §876.1725/Procode: 78 FFX

Dear Mr. Clark:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number: K003580

Device Name: UniTip Gastrointestinal Pressure Sensor Catheter

Indications for Use:

These pressure sensor catheter devices are intended for use in the evaluation and diagnosis of gastroenterological dysfunction related to muscle tonus and the coordination of contractions between muscle groups. The devices are manufactured in the 5 basic model variations listed below. Sphincter of Oddi Manometry catheters are intended for use within the pancreaticobiliary ductal system and Sphincter of Oddi. Gastrointestinal manometry catheters are intended for use in esophageal motility and pH measurement.

1. Basic Sphincter of Oddi Manometry catheter, with 2 sensors

This model variation is intended to aid in determination of the intraluminal pressures within the pancreaticobiliary ductal system and the Sphincter of Oddi. Pressure information is provided at multiple sensor sites. Measurements may be made in conjunction with fluid sampling or injection. However, a catheter lumen is not provided in this model for this purpose.

(Continued on following page)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003580

(Continued)

2. Sphincter of Oddi Manometry catheter, with 2 sensors and aspiration / infusion lumen

This model variation is the same as the Basic Sphincter of Oddi Manometry model described above, except that an aspiration / infusion lumen is added. The aspiration / infusion lumen is provided for convenience of fluid sampling or injection, and the lumen may also be used with a guide wire for positioning.

3. Basic Gastrointestinal catheter, with 4 sensors

This model variation is intended for simple direct esophageal pressure, either at, above, or below the specific site of interest. Pressure information is provided at multiple sensor sites. Pressures may be measured continuously, at rest, or dynamically.

4. Gastrointestinal catheter, with 4 sensors and pH probe

This model variation is the same as the Basic Gastrointestinal (GI) catheter described above, except that this model variation includes a pH probe located at the end of the catheter. The pH probe is added to allow measurement of pH in the stomach or esophagus, as well as providing esophageal pressure information.

5. Gastrointestinal catheter, with 4 sensors and sphincter sleeve

This model variation is the same as the Basic Gastrointestinal (GI) catheter described above, except one of the pressure sensor sites includes a sphincter sleeve. The sphincter sleeve is added to broaden the pressure sensitive zone for the sensor site, and reduce positioning sensitivity. This may be useful where exact sphincter positioning accuracy may be difficult to achieve.